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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,160	11/01/2001	Ronald Alan Coffee	13401	2938
24116 7590 07/16/2010 BATTELLE MEMORIAL INSTITUTE 505 KING AVENUE COLUMBUS, OH 43201-2693				
EXAMINER				
SAMALA, JAGADISHWAR RAO				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/018,160

Applicant(s)

COFFEE ET AL.

Examiner

JAGADISHWAR R. SAMALA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-11, 13-15, 35, 36, 40-42, 59, 60, 71, 73-77, 80-84, 86-94 and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11, 13-15, 35, 36, 40-42, 59, 60, 71, 73-77, 80-84, 86-94 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-840)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 04/30/2010.

- Claims 42, 71, 96 and 98 are currently amended.
- Claims 1-6, 12, 16-34, 37-39, 43-58, 72, 78-79, 95, 97 and 98 have been cancelled.
- Claims 7-11, 13-15, 35-36, 40-42, 59-60, 71, 73-77, 80-84, 86-94 and 96 are pending in the instant application and presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7-9, 11, 13-15, 35-36, 40-42 and 59-60 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are withdrawn in view of Amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The

term "rapidly and completely dissolve on moist surfaces" is a relative term which renders the claims indefinite. The term "rapidly and completely dissolve on moist surfaces" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of disintegration or release of active ingredient in certain time period, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. What time period constitutes rapidly and completely dissolve on what type of moist surfaces. Therefore, one would not know what the metes and bounds of the claims **are maintained** for reason of record in the previous office action filed on 02/10/2010.

Applicant argues that the term "rapid release" (rapid dissolve) or "immediate release" refers to a drug product which has zero-order or first order release of the active agent from the product and which releases the active agent in seconds or minutes rather than hours. This argument is not persuasive since release of active agent in minutes for example 40 or 50 minutes does not constitute as rapid release.

Claim Objections

Claims 61-70 are missing. These set of claims were canceled in the previous filed preliminary amendment dated 11/21/2009. Accordingly, claims 61-70 have been canceled. Also claims 80-84 are dependent on canceled claims. Appropriate correction is needed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-11, 13-15, 35-36, 40-42, 59-60, 71, 73-77, 80-84, 86-94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO-98/03267) in view of Barabas (US 4,704,436), Liu et al (US 6,465,009) and Murray et al (US 6,709,669) **are maintained** for reason of record in the previous office action filed on 02/10/2010.

Applicants arguments filed on 04/30/2010 have been fully considered but they are not persuasive.

Applicant argues that Coffee disclose electrohydrodynamic (EHD) methods, but fails to teach, inter alia, methods that would provide rapid dissolving tablet suitable for buccal delivery as now claimed. As the applicant has stated, the Coffee application

does contain a disclosure for ingestible capsules that may be formed by the EHD process, suitable for oral administration, the examiner will interpret this disclosure as one that sufficiently reads on the limitation of forming tablets in the instant claims. Despite the applicant's characterization that this disclosure of the prior art is an incidental one, it is nevertheless part of the prior art.

Applicant argues that Coffee fails to teach or suggest the steps of supplying a biologically acceptable carrier liquid comprising a solution of a biologically acceptable polymer in a mixture of water and ethanol, wherein said water and ethanol are present in said carrier liquid at a ration of from about 1:0.8 to about 1;1.5 using the EHD comminution.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

In this case, the Coffee patent is relied upon to show that it is known in the art to manufacture capsules by the EHD processing of a bioresorbable polymer, and polyvinyl alcohol, a polymer soluble in water and alcohols (denatured alcohol) using common techniques such as EHD process, while Murray reference shows an equivalence that is recognized in the art for a pharmaceutical composition comprising an active ingredient (e.g., drug) and a carrier (fish gelatin) in the form of a fast-dispersing dosage form which releases the active ingredient rapidly in the oral cavity (e.g., saliva, bodily fluids, water, and the like)

Furthermore, the amount of water and ethanol in a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of water and ethanol in order to achieve the desired results, such as for the preparation of a rapidly dissolvable tablet suitable for buccal delivery of an active agent. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of bisphosphonate concentration would have been obvious at the time of Applicant's invention. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant argues that the Coffee application teaches fibers or fibrils may actually stick to the surface of skin or soft tissue. However, this would require a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Applicant argues that Coffee disclose methods for the manufacture of microcapsules for inhalation. The reference's teachings are not limited to the examples or preferred embodiments and must be considered as a whole and must be evaluated for what it teaches those of ordinary skill in the art. Microcapsules or fibrils for oral ingestion of appropriate active components enabling release of those components may

also be produced by EHD means by providing the active component as the core of the capsule or fibril.

Applicant argues that neither Liu nor Murray contemplates electrohydrodynamic comminution based methods, and both references teach away from various aspects of the instant invention. This argument is not persuasive since these references are combined for their teachings of knowledge in the art of manufacture of rapidly dissolvable tablets comprising active ingredient and polymer polyvinylpyrrolidone such as vinylpyrrolidone-vinyl acetate copolymer and a pharmaceutical composition comprising an active ingredient (e.g., drug) and a carrier (fish gelatin) in the form of a fast-dispersing dosage form which releases the active ingredient rapidly in the oral cavity (e.g., saliva, bodily fluids, water, and the like).

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618

